## REMARKS

### I. Introduction

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

In the specification, paragraph numbers [0012] and [0018] have been amended.

Claims 1, 4, 7, 10-11, and 14 are currently amended.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested. Upon entry of this Amendment, claims 1-19 will remain pending in the application.

### II. Response to Issues Raised by Examiner in Outstanding Office Action

#### A. Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Claims 1-19 are rejected by the Examiner under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite. Applicants respectfully requests reconsideration and withdrawal of the rejection.

The Examiner asserts that the term "about" is a relative term that renders claims 14-19 indefinite. See Office Action, pp. 3-4. The Examiner also asserts that the term "highly" is a relative term that renders claims 11-13 indefinite. See Office Action, pp. 4-5. While Applicants respectfully disagree with these grounds for rejection, claims 11 and 14 have been amended to delete the terms "about" and "highly."

The Examiner asserts that the term "sufficient to regulate and normalize fat metabolism" is a relative expression that allegedly renders claims 1-19 indefinite. See Office Action, pp. 5-6.

A person of ordinary skill in the art would not view the claims as indefinite. Lipid abnormalities are common in patients with diabetes mellitus (Appendix 1). A number of studies demonstrate higher lipid levels in diabetics as compared to non-diabetic persons (Appendices 2, 3). The lipid pattern in an individual is related to glycemic control. Poor glycemic control is associated with hypertriglyceridemia, low HDL-cholesterol, and elevated LDL-cholesterol (Appendix 4). This is true for type 1 and type 2 diabetes.

There is also a close link between obesity, dyslipidemia, and diabetes mellitus. The close connection of these metabolic disturbances is explained by a common pathogenesis. Insulin resistance plays a major role in the development of lipid abnormalities and diabetes mellitus. Therefore, type 2 diabetes is associated with hypertriglyceridemia, low serum HDL cholesterol and high HDL-cholesterol, independent of glycemic control (Appendices 1, 4). These lipid abnormalities can be detected before the onset of overt hyperglycemia and are due to hyperinsulinemia. Dyslipidemia is the consequence of an increased substrate availability, namely glucose and free fatty acids, and decreased lipolysis of very-low-density-lipoprotein triglyceride (VLDL).

The disorders in lipid metabolism of type 2 diabetic patients are highly relevant regarding cardiovascular risk and have two major consequences:

1. Patients with diabetes and pre-diabetes have to be regularly screened for lipid abnormalities. In hyperlipidemia, a treatment is necessary to reduce the risk of cardiovascular disease. Both hyperglycemia and hyperlipidemia are independent cardiovascular risk factors.

2. Since the risk for cardiovascular disease is increased in diabetic patients, lipid abnormalities have additional importance. Therefore, lipid level targets differ between diabetic and non-diabetic persons. The American Diabetes Association (Appendix 5) has

defined special targets of lipid values for diabetic patients, thus allowing one to distinguish between normal fat metabolism and the fat metabolism of diabetic patients; see, e.g., page 569, 1st column, 2nd and 3rd full paragraph, page 570, 2nd column, and sections "conclusions" and "recommendations." These sections indicate that for the regulation and normalization of fat metabolism the following values are relevant: LDL < 100 mg/dl, HDL >50/dl, and triglycerides < 150 mg/dl. In other words, the term "sufficient to regulate or normalize said metabolism" has a clear and definite meaning to a person skilled in the art.

Consequently, a person of ordinary skill in the art would understand the scope of the claims and not view them as indefinite. Applicants respectfully request reconsideration and withdrawal of these rejections.

**B. Claim Rejections - 35 U.S.C. § 102**

Claim 1 is rejected by the Examiner under 35 U.S.C. § 102(b) as being allegedly anticipated by Bell et al. (WO 97 38593) ("Bell"). Applicants respectfully request reconsideration and withdrawal of the rejection.

The Examiner asserts that Bell teaches a dietary supplement bar for the treatment of nighttime hypoglycemia in a diabetic patient, wherein the bar includes 2-40% by weight lipid, and a lipid source in a dietary supplement sufficient to delay gastric emptying. See Office Action, p. 6.

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently. *In re Schreiber,* 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed.Cir.1997). Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *Scaltech, Inc. v. Retec/Tetra L.L.C.*, 156 F.3d 1193 (Fed.Cir. 1999). Occasional results are not inherent. *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1365 (Fed.Cir. 1999).

The present fact pattern resembles that present in *Rapport v. Dement*, 254 F.3d 1053 (Fed.Cir. 2001). In *Rapport*, a method of treating a patient for a condition (sleep apnea) was allowed over an inherency rejection. In the past, the drug was provided for patients to be taken three times a day for a different condition (severe alveolar hyperventilation). The court rejected U.S. Patent and Trademark Office's anticipation arguments that since the drug was given multiple times during the day, patients would have taken it close to sleep and the drug would, therefore, have inherently been used to treat sleep disorders. Id., at 1062. The court found no basis for anticipation. Id. First, the court pointed out that the condition in the prior art reference has no relationship to sleep apnea. Id. Second, even though the same drug was used and might have been used close to sleep, the court found there were two speculative assumptions that had no basis in the prior art: (1) that the treatment regimen would necessarily include an administration "at the time of sleep", and (2) that administering two 10 mg doses of the drug throughout the day would necessarily result in a "therapeutically effective amount" of the drug for treating sleep apnea. Even when the 10 mg of drug was provided three times a day and the preferred range for treating sleep apnea was 20-40 mg, the court would not find anticipation based on prior art. Id. at 1062-1063.

In the present case, the Examiner alleges that because a bar was used to treat nighttime hypoglycemia, the claimed method to regulate and normalize fat metabolism, in general, for diabetics is anticipated. Anticipation is not a matter of probabilities. There is no evidence that the nighttime administration of the bar to treat hypoglycemia, according to Bell, necessarily results in a therapeutic amount sufficient to regulate and normalize fat metabolism. As described below, the holding and reasoning in *Rapport* argues against a case of anticipation.

For Bell, the problem underlying the invention is not the regulation and normalization of lipid metabolism in patients with diabetes. Rather the problem relates to the treatment or prevention of nighttime hypoglycemia (see, for example, Bell, page 2, lines 16-17). For this purpose a "bar" as a supplement was developed containing about 10 to 60% simple carbohydrates (see Bell, page 2, lines 21-25, and claim 1). The main feature of the bar relates

to the composition of the carbohydrates. The central importance of the carbohydrates is apparent from Bell at page 2, lines 1-9:

> Accordingly, an object of the invention is to provide a novel diabetic supplement bar which allows constant bloodstream glucose level during the night, thus preventing nighttime hypoglycemia in a diabetic patient.
>
> Another object of the invention is to provide a method of preventing or treating nighttime hypoglycemia in a diabetic patient by administering the diabetic supplement bar of the invention.
>
> A further object of the invention is to control nighttime blood sugar levels of diabetic patients by administering the diabetic supplement bar of the invention near bedtime which provides phased released of glucose in the bloodstream.

The further components of the "bar," i.e. lipids and carbohydrates, are of minor importance. In fact, lipids are only described in two lines of the specification as comprising medium-chain triglyceride and long-chain triglycerides.

Bell does not disclose the use of MCT for the regulation and normalization of lipid metabolism of patients having diabetes, but merely the prevention of a nighttime hypoglycemia by use of a bar having a defined carbohydrate composition. As noted in *Rapport*, a first consideration for inherency is whether the drugs are being used to treat the same condition. Bell relates to a medical condition which fundamentally differs from the medical condition of the present invention.

The second consideration of *Rapport* is whether the prior art necessarily results in a therapeutically effective amount of the claimed drug. Bell is completely silent on the issue of lipid metabolism and, as noted above, is not directed to the control of lipid metabolism. The only concern of Bell is carbohydrate release during the night. The Examiner notes that Bell discloses the use of "amounts sufficient to delay gastric emptying" which may be up to 40% of the total weight. However, there is no evidence that the delay of gastric emptying correlates with the regulation and normalization of lipid metabolism.

The Examiner alleges that the Applicant must prove this correlation does not exist because of MPEP §2113. However, MPEP §2113 relates to product-by-process claims. Applicants note the deleted portions of the MPEP and the case cited by the examiner:

> THE USE OF 35 U.S.C. 102/ 103 REJECTIONS FOR **PRODUCT-BY-PROCESS CLAIMS** HAS BEEN APPROVED BY THE COURTS
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> "[T]he lack of physical description in a **product-by-process claim** makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a **product-by-process claim**, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

None of the present claims are product by process claims and there is, therefore, no basis to shift the burden on to the Applicant for evidence the patent office must supply.

There is no evidence in Bell that the bar described will necessarily affect lipid metabolism. Although the bar may contain MCT, anticipation is not about probabilities. In *Rapport*, a drug was provided to patients during the day for one condition (severe alveolar hyperventilation), but no evidence that the drug was provided at night or in an effective amount for a different condition (sleep apnea) could be found. In the present case, the bar, as provided, by Bell, is to be taken at night for one condition (hypoglycemia), but no evidence that the MCT could provide an effective amount for a different condition (lipid regulation and normalization) throughout the entire day is provided. Thus, Bell does not anticipate claim 1 and withdrawal of this ground for rejection is respectfully requested.

### C. Claim Rejections - 35 U.S.C. § 103

Claims 1-19 are rejected by the Examiner under 35 U.S.C. § 103(a) as being alleged;u obvious over Bell, The Merck Index, Zawistowski, Laughlin, Stedman's Medical Dictionary,

Mendy, and DeMichele. Applicants respectfully request reconsideration and withdrawal of the rejection.

The Examiner asserts that some of the limitations in the claims are not provided in Bell, but would be obvious when combined with the remaining references. These differences include:

(i) the use of oleic acid or linoleic acid as unsaturated triglycerides;

(ii) the use of alpha-linolenic acid, eicosapentaenoic acid and/or docosahexaenoic acid;

(iii) the use of butter flavor or additional vitamins and nutrients, including, fat-soluble vitamins, beta-carotene, folic acid, zinc, chromium or manganese, for example, as recited in present claims 11-14 and 15-19; and

(iv) the presently claimed dosage amounts of triglycerides, fatty acids or additional nutrients and the presently claimed percentages of the fat phase versus the aqueous phase of the composition as recited in the present claim 14.

Office Action at p. 9. The Examiner concedes that the presently claimed dosages of MCT, saturated long-chain triglycerides, or any one or more of the vitamins or minerals recited in claims 11-13 and 15-19 are not disclosed. See Office Action at p. 14. These statements are equally applicable to the specific dosage provided in claim 2 for MCTs.

To establish a *prima facie* case of obviousness, there needs to be: (1) some suggestion or motivation to modify the reference or to combine reference teachings, (2) a reasonable expectation of success, and (3) the prior art references, when combined, must teach or suggest all the limitations of the claimed invention. *See* MPEP §2143 (Aug. 2001). "Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). The examiner has not met his burden.

As noted above, Bell does not relate to the control of lipid metabolism. Applicants refer the Examiner to the arguments above showing that Bell describes the treatment of hypoglycemia. Consequently, in the present case the combination of teachings between Bell and the other cited references do not substantiate an obviousness rejection. In response to the Examiners numbered points:

(i) The Examiner combines Bell and the Merck Index. The Merck index does not describe lipid metabolism and cannot supplement this deficiency in Bell. There is no motivation to combine these teachings in the context of diabetic lipid metabolism.

(ii) The Examiner combines Bell with Zawistowski and the Merck Index. Zawistowski mentions the use of long chain triglycerides in the treatment of diabetes. Applicants claim methods of using compositions comprising MCTs (claim 1) and compositions with 10-30% MCTs (claims 2-19). The prior art references must teach each element of a claim to be a proper obviousness rejection. Nothing in Bell, Zawistowski, or Merck leads to the present MCT claim limitations. A concentration of 10-30% MCT is not provided in Bell. Zawistowski does not motivate a person of skill in the art to alter the MCT concentration, as Zawistowski discusses the use of long chain triglycerides. Moreover, Merck does not cure these deficiencies.

(iii) Bell is combined with Laughlin, Stedman's, Mendy, and DeMichele. These supplemental references relate to vitamins and other additives in the composition. None of these references motivate a person of skill in the art to use the supplement in the context of lipid metabolism. In addition, none of the references teach the specific dosages of MCT or cure the other deficiencies described above.

(iv) Bell is not combined with a reference. Rather the Examiner asserts that the determination of optimum dosage would lead to the claimed invention. Applicants have discussed above that Bell relates to hypoglycemia. There is no evidence that optimum dosages for hypoglycemia and gastric emptying have any relationship to lipid normalization and metabolism. In addition, the Examiner asserts that different characteristics of individuals

will lead to differing compositions of the bar which would be consistent with the claimed invention. No evidence is offered to substantiate how the differing characteristics enumerated by the Examiner affect the composition makeup or necessarily lead to the claimed method. As noted above, there is no evidence that the changes to a bar in the context of hypoglycemia would lead to the composition of the supplement for the normalization o lipid metabolism. Any changes to Bell by a person of skill in the art would relate to hypoglycemia and not lipid metabolism.

Applicants respectfully request reconsideration and withdrawal of this objection..

## CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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